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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/101,825 07/17/98 GRONHOJ LARSEN

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EXAMINER

HAMUD, F

ART UNIT

PAPER NUMBER

1646

14

DATE MAILED: 03/30/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action SummaryApplication No.
09/101,825Applicant
Larsen et alExaminer
Fozia HamudGroup Art Unit
1646☒ Responsive to communication(s) filed on Dec 21, 1999☐ This action is **FINAL**.☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims☒ Claim(s) 18-64 is/are pending in the application.Of the above, claim(s) 44 and 57-60 is/are withdrawn from consideration.☐ Claim(s) _____ is/are allowed.☒ Claim(s) 18-43, 45-56, and 61-64 is/are rejected.☐ Claim(s) _____ is/are objected to.☐ Claims _____ are subject to restriction or election requirement.**Application Papers**☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.☐ The drawing(s) filed on _____ is/are objected to by the Examiner.☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.☐ The specification is objected to by the Examiner.☐ The oath or declaration is objected to by the Examiner.**Priority under 35 U.S.C. § 119**☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been☐ received.☐ received in Application No. (Series Code/Serial Number) _____☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).**Attachment(s)**☒ Notice of References Cited, PTO-892☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3,5☐ Interview Summary, PTO-413☒ Notice of Draftsperson's Patent Drawing Review, PTO-948☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

1. Applicant's election with traverse of Group I (claims 18-46, 48) and the prevention and treatment of pancreatitis as the species to examine, in Paper No.13 filed on December 2, 2000 is acknowledged.

3. Receipt of Applicant's amendments filed in Paper Nos.7, 8, 11, on 7/29/98, 7/29/98 and 12/21/99, respectively is acknowledged. Claims 1-17 have been canceled and new claims 18-48 have been added in the amendment filed in Paper No.8, on 7/29/98. New claims 49-64 have been added in the amendment filed in Paper No.8 on 12/21/99.

The traversal is on the grounds, that this application is a national stage of a PCT application, PCT rules apply, therefore, the restriction between Groups I and II is improper because the process of Group II (claim 47) is specially adapted to the production of Group II polypeptide (claim 18). This traversal is deemed persuasive, therefore, Groups I and II will be examined together.

Claims, 44, and 57-60 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected species.

Specification

3a. It is noted that this application appears to claim subject matter disclosed in prior PCT Application No. PCT/DK97/00021, filed on 07/16/97, now WO 9726279 (issued on 07/24/97). A reference to the prior application must be inserted as the first sentence of the specification of this application if Applicant intends to rely on the filing date of the prior application under 35 U.S.C. 120. See 37 CFR 1.78(a).

It is suggested that below the title of the invention be inserted:

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Cross Reference to Related Applications

"This Application is a 371 of WO 9726279".

Appropriate correction is required.

3b. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b).

An abstract on a separate sheet is required.

3c. The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) Title of the Invention.
- (b) Cross-References to Related Applications.
- © Statement Regarding Federally Sponsored Research or Development.
- (d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
- (e) Background of the Invention.
 - 1. Field of the Invention.
 - 2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) Brief Summary of the Invention.
- (g) Brief Description of the Several Views of the Drawing(s).
- (h) Detailed Description of the Invention.
- (I) Claim or Claims (commencing on a separate sheet).
- (j) Abstract of the Disclosure (commencing on a separate sheet).
- (k) Drawings.
- (l) Sequence Listing (see 37 CFR 1.821-1.825).

The "Figure legends" is placed on page 27 of the instant specification, however, this should be titled "Brief Description of the Figures" and should be placed between the summary of the invention and the detailed description of the invention. Appropriate correction is required.

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Claim Rejections - 35 U.S.C. § 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4a. Claims 18-39, 48 and 55, are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 18-42 recite "a polypeptide amounting...." which encompasses the polypeptide as it occurs in nature. However, since Applicants do not intend to claim a naturally occurring product amendment of the claims to show the hand of man would obviate this rejection. It is suggested that claims 18-39, 48 and 55 be amended to recite " an isolated polypeptide...". Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5a. Claims 18-43, 45-56, and 61-64 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated peptide comprising the following amino acid sequence Thr-X₄-Lys-X₅-Arg-X₆, as set forth in SEQ ID Nos:1, 19-22, said peptide corresponding to a nonapeptide sequence from the C-terminal end of hIL-10, and possessing activities which mimic those of hIL-10, including, activities recited in sub-parts (a-k) of claim 18, said peptide exhibiting at least one of the conditions, set forth in claim 18, (I-V), and a method of treating pancreatitis and ARDS by administering said nonapeptide, does not reasonably provide enablement for a polypeptide

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amounting up to about 100, 30, 20, 15, 14, 13, 12, 11 or 10 amino acids which comprise the amino acid sequence SEQ ID NO:1, 19-22, or a peptidomimetic modeled on the basis of formula of SEQ ID NO:19. The instant specification is also non-enabling for a method of treating or preventing any of the diseases recited in claims 42 or 56, or a method of *preventing* pancreatitis and ARDS by administering said nonapeptide, or a method of preventing or treating a disease which is preventable or treatable by "all" possible substances which have at least one of the properties recited in a-k of claim 49. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim 18 recites "a polypeptide amounting up to about 100 which comprises the sequence set forth in SEQ ID No:19 which", however, the instant specification discloses that the polypeptide of the instant invention is a nonapeptide corresponding to the C-terminal end of hIL-10 (SEQ ID NO:1), said nonapeptide possessing some immuno-suppressive activities which mimic those of hIL-10, (see page 9, lines 20-30). The specification also discloses that the nonapeptide of the instant invention is very potent in inducing different functions, is very stable, and it couples with the IL-10 receptor correctly, (page 9, lines 31-33). The specification also teaches that a nonapeptide is chosen because generally a 9 amino acid polypeptide sequence is unique for a protein, but that the last 6 amino acid residues of hIL-10 seem to be the most important ones, (page 10, lines 1-5). Thus the instant specification is only enabling for an isolated peptide consisting of the amino acid sequence set forth in SEQ ID NOs:1, or 19-22, with the specific amino acid substitutions recited in claims 18-22, and shown in SEQ ID NOs:19-22. The instant specification is non-enabling for "all possible"

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polypeptides that amount up to about 100, 30, 20, 15, 14, 13,12, 11 or 10 amino acids, that comprise the amino acid sequence set forth in SEQ ID Nos:19-22, or any peptidomimetic modeled on the basis of the formula of SEQ ID NO:19. The specification only enables a nonapeptide (IT9302, SEQ ID Nos:1) having the amino acid variations shown in SEQ ID Nos: 19-22, said nonapeptide having specific characteristics and properties. These properties differ structurally, chemically and physically from other known polypeptides. By application of the factors set forth in Ex parte Forman (230 USPQ 546 (Bd. Pat. App. & Int. 1986), and reiterated in In re Wands (858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)), which include (1) quantity of experimentation, (2) guidance presented, (3) the predictability of the art, and (4) the breadth of the claims, in the instant application, the quantity of experimentation to determine, if "all possible" peptides that amount in total up to about 100 amino acid residues which comprise the amino acid sequences set forth in SEQ ID NO:19-22, or "all" possible peptidomimetics modeled on the basis of the formula of SEQ ID NO:19, would retain the desired biological activities of the nonapeptide of the instant invention. Furthermore, Applicants do not teach where in the claimed polypeptide amounting in total up to about 100, 30, 20, 15, 14, 13,12, 11 or 10 amino acids, should the 9 amino acid residues of SEQ ID Nos:19-22, be located, at N-terminus, in the middle or at the C-terminus of the polypeptide. Therefore, it would require undue experimentation to determine which of all the possible polypeptides amounting in total up to 100 100, 30, 20, 15, 14, 13,12, 11 or 10 amino acids which comprise the amino acid sequences set forth in SEQ ID Nos:19-22, that are encompassed by the scope of the claims, would have the desired biological activities of the nonapeptide of the instant invention, i.e, induce inhibition of spontaneous IL-8 production by human monocytes, induce production of interleukin-1 receptor

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antagonistic protein(IRAP) by human monocytes, etc. The disclosure of the polypeptides with the amino acid sequence set forth in SEQ ID NO:1, 19-22, with the specific amino acid substitutions recited in claims 19-22, is clearly insufficient support under the first paragraph of 35 U.S.C. § 112 for claims which encompass every and all polypeptides amounting in total up to about 100, 30, 20, 15, 14, 13,12, 11 or 10 which comprise the amino acid sequences set forth in SEQ ID Nos: 19-22, or peptidomimetic modeled including mutants thereof.

Furthermore, the amount of embodiments corresponding to the desirable polypeptides, may be innumerable, and the enabled embodiments amount to only the nonapeptide of SEQ ID Nos:1, 19-22, said nonapeptide having similar biological to hIL-10. Given the knowledge in the art regarding the unpredictable nature of getting biologically active peptides, as well as a lack of guidance and working examples in the specification, the skilled artisan would not have a reasonable expectation of success that any polypeptide amounting up to about 100, 30, 20, 15, 14, 13,12, 11 or 10 which comprises the amino acid sequences set forth in SEQ ID Nos:19-22 would have the desired biological activities, and thus it would require undue experimentation to practice this invention as claimed. Applicants do not disclose what are the other, for example, 91 amino acid residues that the claimed polypeptide amounting in total up to 100 amino acids, is composed of. Applicants do not teach if the nonapeptide of the instant invention should be from amino acid residue 1 to amino acid residue 9, from amino acid residue 45 to amino acid residue 53, from amino acid residue 91 to amino acid residue 100, of the 100 amino acid polypeptide, neither do they demonstrate if the claimed polypeptide would retain its activity regardless of where the nonapeptide is located.

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With respect to claims 43, 45-46, which recite “a method of treating or preventing pancreatitis, the method comprising administering to a patient in need thereof a therapeutically effective a polypeptide amounting in total up to about 100 amino acids which comprises the sequence set forth in SEQ ID NO:19...”, what is claimed is a method of treating or preventing pancreatitis by administering “all” possible polypeptides amounting in total up to 100, 30, 20, 15, 14, 13, 12, 11 or 10 amino acids which comprise the sequence Set forth in SEQ ID NO:19, however, the instant specification discloses that the nonapeptide (IT9302) of the instant invention, causes dose-dependent inhibitory effect on processes which reflect pro-inflammatory activities, and that it suppresses the spontaneous production of IL-8 by human monocytes, inhibits production of IL-8 production induced by IL-1, inhibits IL-8 induced migration of monocytes and/or T cells, (page 40, lines 12-35). Therefore, the instant specification is only enabling for a method of treating pancreatitis by administering the peptide with the amino acid sequence depicted in SEQ ID Nos:1, 19-22. The instant specification does not disclose any polypeptide, other the one set forth in SEQ ID Nos: 1, 19-22, that is used to treat pancreatitis, nor does it disclose any polypeptide amounting in total up to 100 amino acids which comprise the sequence Set forth in SEQ ID NO:19 for treating said disease, and it would be undue experimentation to determine “all” the possible polypeptides that may be used for said treatment.

With respect to claims 49-54 which recite “a method of treating a disease which is treatable by a substance which has at least one of the properties recited in claim 49, (a-K)...”, what is claimed is a method of treating pancreatitis by administering “all” possible substances which have at least one of the properties recited in sub-parts (a-k) of claim 49, however, the instant specification

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demonstrates that the only enabled nonapeptide (SEQ ID NOs:1, 19-22) of the instant invention has at least one of the properties recited in claim 49 (a-k), and that said peptide may have therapeutic activities. The instant specification does not disclose any other substance that has any of the properties recited in claim 49(a-k), or may have therapeutic values. Therefore, the specification is only enabling for a method of treatment by administering the nonapeptide (SEQ ID NOs:1, 19-22).

With respect to claims 42 and 56 the instant specification is only enabling for a method of treating diseases that involve pro-inflammatory activities, by administering a pharmaceutical composition comprising the nonapeptide sequence set forth in SEQ ID Nos1, :19-20, because the instant specification discloses that the nonapeptide of the instant invention mimics IL-10 activity, and may have therapeutics values in diseases where IL-8, MCAF, IL-1 are believed to have pathogenic roles, (page 41, lines 26-30). Thus the instant specification is only enabling for a method of treating diseases that involve pro-inflammatory activities, i.e IL-8 and TNF α production, monocyte or T cell migration, said method comprising administering the peptide of nonapeptide (SEQ ID NOs:1, 19-22), and is non-enabling for a method of treating all possible diseases by administering said peptide.

With respect to claims 42-43, 45-46, 49-54 and 56 which recite "a method of preventing ..", the instant specification is non-enabling for a method of *preventing* any disease, it does not show any examples where any disease is "prevented" by administering the peptide of the instant invention.

Claims 19-21, 27, 32, 34-39, and 61-64 are rejected 35 U.S.C. § 112, first paragraph, insofar as they depend on claim 18.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claims 18-43, 45-56, 61-64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5a. Claims 18, 22, 48, 54-55 recite "a polypeptide amounting in total up to about 100", about, renders the claims indefinite, because there is no upper or lower limit for the length of the claimed polypeptide. Should the claimed polypeptide comprise, 99 or 120 amino acid residues, or something else? Appropriate correction is required.

5b. Claim 18 recites the limitation ".....the TNF α" in sub-part (j). There is insufficient antecedent basis for this limitation in the claim.

5c. Regarding claim 47, the phrase "optionally" recited in line 5, renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention.

See MPEP § 2173.05(d).

Claims 19-21, 23-43, 46, 49-53, 56 and 61-64 are rejected 35 U.S.C. § 112, second paragraph, insofar as they depend on claim 18.

Claim rejections-35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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6a. Claims 18-26, 48, 55 are rejected under 35 U.S.C § 102(b) as being anticipated by Vieira et al (February/1991).

Vieira et al teach the isolation and expression of human IL-10, said hIL10 comprising 160 amino acid residues, (see abstract and page 1174, column 1). The hIL-10 disclosed by Vieira et al is stabilized, purified and comprises the sequences set forth in SEQ ID Nos: 1, 19-20, of the instant application recited in claims 18-27, 48 and 55.

Claims 18-27, 48, 55 of the instant application are drawn to a polypeptide amounting in total up to about 100, 30, 20, 15, 14, 13, 12, 11, 10 amino acids which comprise the sequences set forth in SEQ ID Nos: 1, 19-22. Therefore, since the hIL-10 disclosed by Vieira et al comprises the amino acid sequences set forth in SEQ ID NOS:1, 19-22, the Vieira et al reference anticipates the instant claims 18-27, 48, 55. Furthermore, the properties recited in claim 18, (a-k), are inherent properties of the hIL-10 disclosed by Vieira et al.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7a. Claims 18 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vieira et al (02/91) in view of Kent (1988).

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The teachings of Vieira et al have been set forth in paragraph 6a of this office action. However, Vieira et al do not teach a process for synthesizing the claimed polypeptide by using solid-phase peptide synthesis (SPPS).

Kent discloses a method of synthesizing a desired peptide by utilizing a stepwise solid phase synthesis, (see page 961). The method disclosed by Kent involves the attachment of the C-terminal amino acid to a solid support and the addition of the subsequent amino acids in a stepwise fashion, (page 961).

It would have been prima facie obvious at the time of the invention to synthesize the hIL-10, (which comprises the amino acid sequence set forth in SEQ ID NO:19), disclosed by Vieira et al using the method of solid phase peptide synthesis taught by Kent, because Kent teaches that the stepwise solid phase synthesis is a simple technique which has fundamental physical and chemical advantages over the solution approach, especially the attachment of a protected peptide to a swollen resin support overcomes the poor solubility of a protected peptide intermediates, (see Kent page 961). One of ordinary skill in the art would have been motivated at the time of the instant invention to synthesize the hIL-10 disclosed by Vieira et al by the method taught by Kent, because chemical synthesis of peptides allows the systematic variation of structure with the aim of developing peptides for therapeutic use.

7b. Claims 18, 43, 45-46, 49-54, 61-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vieira et al (02/91) in view of Van Laethem et al (06/1995).

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The teachings of Vieira et al have been set forth in paragraph 6a of this office action. However, Vieira et al do not teach a method of treating pancreatitis, said method comprising administering to a patient in need thereof, a therapeutically effective amount of the peptides of SEQ ID Nos:1, 19-22.

Van Laethem et al teach that IL-10 is a major anti-inflammatory cytokine that inhibits the secretion of pro-inflammatory cytokines by monocytes and/or macrophages, (see abstract). Van Laethem et al disclose in a mice pancreatitis model where pancreatitis was induced by retrograde injection in the pancreatic duct of sodium taurocholate , and showed that IL-10 pretreatment decreases the severity of experimental acute pancreatitis by inhibiting development of cellular necrosis, (see page 1921, last paragraph). Van Laethem et al showed that IL-10 inhibited secretion of pro-inflammatory mediators, (page 1921).

It would have been prima facie obvious at the time of the invention to design a method of treating pancreatitis, said method comprising administering to a patient in need thereof, a therapeutically effective amount of the hIL-10, (comprising the amino acid consensus set forth in SEQ ID NO:19), disclosed by Vieira et al, because Van Laethem et al teach that IL-10 was able to decrease the severity of experimental acute pancreatitis, by inhibiting the secretion of pro-inflammatory cytokines such as local tumor TNF α . One of ordinary skill in the art would have been motivated at the time of the instant invention to design a method of treating pancreatitis, said method comprising administering to a patient in need thereof, an effective amount of the hIL-10 disclosed by Vieira et al (which comprise the amino acid sequence set forth in SEQ ID NO:19), because Van Laethem et al, established that IL-10 decreases the severity of experimental acute pancreatitis and suggest that IL-10 may have potential therapeutic uses.

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7c. Claims 18, 33, 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vieira et al (02/91) in view of Barrett et al (US Patent 5,654,276).

The teachings of Vieira et al have been set forth in paragraph 6a of this office action. However, Vieira et al do not teach a peptide, which is cyclized, or wherein the amino terminal amino acid residue is acylated, or wherein the carboxyterminal amino acid residue is amidated.

Barrett et al teach peptides that bind to interleukin-5 receptor, said peptides synthesized by using standard solid phase synthesis, (column 15, lines 34-54), wherein said peptides are cyclized, or wherein, the amino acid residue at the Carboxy terminus is amidated or the amino acid residue at the Amino-terminus is acylated, (column 17, line 15 through column 18 line 65).

It would have been prima facie obvious at the time of the invention to generate modified peptides of the hIL-10 disclosed by Vieira et al comprising the sequences set forth in SEQ ID Nos: 1, 19-22, because Barrett et al teach, modifying the C-terminal or the A-terminal amino acid residues, so that there is no terminal amino or carboxyl group, induces the peptide to cyclize, thus decreasing the peptide's susceptibility to proteases or to restrict the conformation of the peptide, (column 19, 10-15). One of ordinary skill in the art would have been motivated at the time of the instant invention to design cyclic peptides comprising the hIL-10 disclosed by Vieira et al (which comprise the amino acid sequence set forth in SEQ ID NO:19), because IL-10 is a major anti-inflammatory cytokine.

Conclusion

No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia Hamud whose telephone number is (703) 308-8896. The

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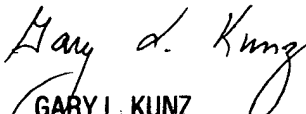
examiner can normally be reached on Monday-Friday from 8:00AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Fozia Hamud
Patent Examiner
Art Unit 1646
March 22, 2000


GARY L. KUNZ
PRIMARY EXAMINER
GROUP 1200